

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2005/010036

International filing date (day/month/year)

24.03.2005

Priority date (day/month/year)

31.03.2004

International Patent Classification (IPC) or both national classification and IPC

A61M5/315

Applicant

COOK INCORPORATED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010036

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010036

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-6,11-23,25
	No: Claims	1-2,7-10 and 22-24
Inventive step (IS)	Yes: Claims	
	No: Claims	1-25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: US-A-4 940 459 (NOCE ET AL) 10 July 1990 (1990-07-10)
- D2: US-A-4 312 343 (LEVEEN ET AL) 26 January 1982 (1982-01-26)
- D3: WO 2004/002375 A (TECRES S.P.A; FACCIOLI, GIOVANNI; SOFFIATTI, RENZO) 8 January 2004 (2004-01-08)
- D4: WO 01/93787 A (COOK INCORPORATED; SABIN CORPORATION) 13 December 2001 (2001-12-13)
- D5: US-A-5 927 562 (HAMMEN ET AL) 27 July 1999 (1999-07-27)
- D6: US 2002/016603 A1 (WELLS TIMOTHY N) 7 February 2002 (2002-02-07)
- D7: WO 95/22941 A (MINNESOTA MINING AND MANUFACTURING COMPANY) 31 August 1995 (1995-08-31)
- D8: US 2002/032447 A1 (WEIKEL STUART ET AL) 14 March 2002 (2002-03-14)
- D9: US-A-3 212 685 (SWAN RICHARD JAMES ET AL) 19 October 1965 (1965-10-19)
- D10: EP-A-0 919 206 (CENTRIX, INC) 2 June 1999 (1999-06-02)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-2, 7-10 and 22-24 is not new in the sense of Article 33(2) PCT. Furthermore, none of the claims 3-6, 11-21 and 25 contain any inventive subject-matter (Article 33(3) PCT).

2.1. The document D1 discloses (the references in parentheses applying to this document):

A high pressure dispenser for the application of a medicinal mixture to a desired location (figs. 1-4), the dispenser comprising:

a handle (item 22);

a chamber that receives medicinal mixture coupled to the handle (item 20);

a threaded region within the handle (item 28);

a threaded rod in threaded engagement with the threaded region (item 24);

a knob coupled to the threaded rod (item 46); and
at least one insert-molded component, wherein the at least one insert-molded component includes at least one of a threaded insert providing the threaded region insert molded into the handle and a threaded rod insert molded into the knob (col. 4, lines 31-43).

The subject-matter of claim 1 is therefor not new (Article 33(2) PCT)

2.2. Claim 22 is also not novel (Article 33(2) PCT) as its features are disclosed in D9 (see fig. 1, items 1-10, claim 1).

2.3. Furthermore, it is regarded that the difference between claim 1 and the prior art injectors in D2-D4 (see citations in search report), i.e. the insert molded component, is trivial as it is known to the person skilled in the art to have an insert molded into plastic (see D5, citations in search report). Therefore, should he want to increase the strength of the one or both of the threaded parts, he would use a strong insert which would be molded into the knob or the handle. Hence, this standard manufacturing procedure can not render claim 1 inventive (Article 33(3) PCT) over the combinations of the documents D2-D4 with document D5, or even common general knowledge.

2.4. Correspondingly, the other independent claims 12, 18 and 22 are also not inventive (Article 33(3) PCT) because the differences to the prior art dispensers (D2-D4), such as overmolded soft rubber to provide better grip (claim 12), tab and notch for locking the connection of chamber and handle (claim 18) and smooth concave surface between the cylindrical surface and the nozzle of the chamber to reduce flow resistance (claim 22) are trivial and within the common general knowledge of the person skilled in the art. Furthermore, they are also known from D6-D10 (see references in search report).

3. Dependent claims 2-11, 13-17, 19-21 and 23-25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since all the features contained in these claims are not only trivial design options within the common general knowledge of the person skilled in the art but they are also disclosed in D1-D10 (see corresponding passages cited in the search report).

Re Item VII

Certain defects in the international application

4. Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).
5. Documents D1-D4 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII

Certain observations on the international application

6. Claims 1, 12, 18 and 22 have been drafted as independent claims and have at least partly overlapping scope. Drafting such a plurality of independent claims with overlapping scope makes it impossible to clearly delimit the subject matter which could represent the invention for which protection is sought, so that the claims as a whole fail to comply with the clarity and conciseness requirements of Article 6 PCT.
7. Claims 10 and 22-24 are not clear (Article 6 PCT) since any surface could be regarded to be smooth. In fact it would be very difficult to manufacture a syringe such that it would not have a gradual transition between the cylindrical surface and the nozzle.

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